

B. Statement of Grounds

12. Proposed Labeling

CLINICAL STUDIES

Primary Prevention of Myocardial Infarction (MI): Five clinical studies have been conducted evaluating aspirin for prevention of a first MI in over 55,000 patients with different levels of baseline risk. Analyses of these studies demonstrated a range of 28-32% reduction in the combined outcome of nonfatal MI, fatal MI, and sudden death.

INDICATIONS AND USAGE

Vascular Indications (Ischemic Stroke, TIA, Acute MI, Prevention of Recurrent MI, Unstable Angina Pectoris, Chronic Stable Angina Pectoris, and Prevention of First MI): Aspirin is indicated to: (1) Reduce the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, (2) reduce the risk of vascular mortality in patients with a suspected acute MI, (3) reduce the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, (4) reduce the combined risk of MI and sudden death in patients with chronic stable angina pectoris, and (5) reduce the risk of a first myocardial infarction in patients with a CHD risk of 10% over 10 years or in patients for whom there is positive benefit-risk as assessed by their health care provider.

DOSAGE AND ADMINISTRATION

Prevention of first MI:

75-325 mg once a day. Continue therapy indefinitely.